



ALOFISEL®
(darvadstrocel)

Mode of administration

〔GUIDE for SURGEONS〕



ALOFISEL®

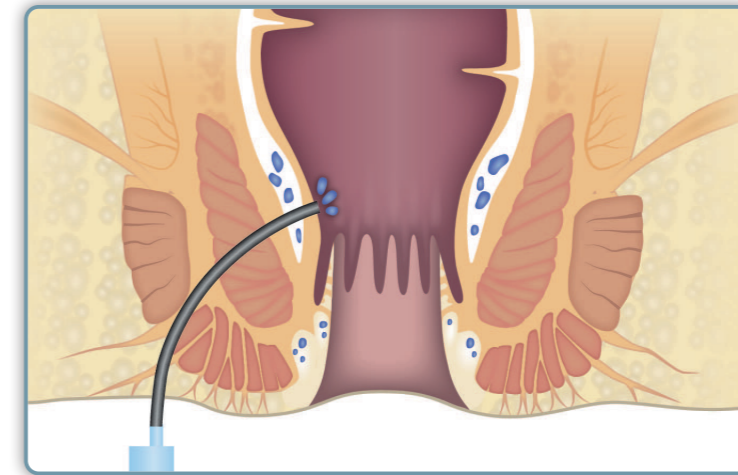
- Alofisel® is a dispersion of expanded human adipose stem cells, indicated for the treatment of complex perianal fistula(s) in adult patients with non-active/mildly active luminal Crohn's disease, when fistula(s) have shown an inadequate response to at least one conventional or biologic therapy. Alofisel® should be used only after conditioning of the fistulas.
- Alofisel® is for injection in the fistula tract tissue in a surgical environment under general or regional anesthesia.
- A single dose of Alofisel® consists of 120 million cells. The dose is provided as 4 vials, containing 30 million cells in 6 mL dispersion each.



- Alofisel® mode of use comprises 2 main steps:
 1. Fistula conditioning.
 2. Product administration (preparation and injection).
- It is recommended that at least 2 to 3 weeks before the administration day, preparatory surgery is performed comprising exploration (under anaesthesia) of fistula.

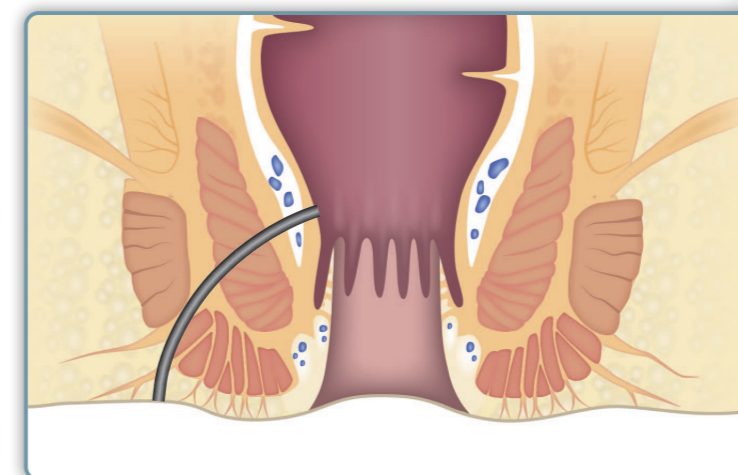
FISTULA CONDITIONING

- Prior to injecting Alofisel®, condition the fistula according to the following steps:
 1. If setons are in place, remove them.
 2. Characterize the fistula and identify the location of the internal opening(s). This can be done by injecting saline solution through the external opening(s) until it exits via the internal opening(s).

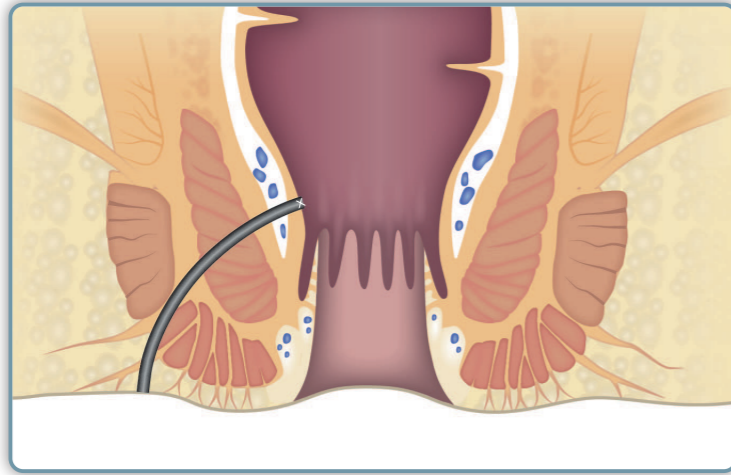


Injecting agents other than saline solution (e.g. hydrogen peroxide, methylene blue, iodine solutions or hypertonic glucose) is not allowed, as they compromise the viability of the cells to be injected.

3. Vigorously scrape all fistula tracts using a metallic curette with special emphasis on the internal opening(s) area(s).



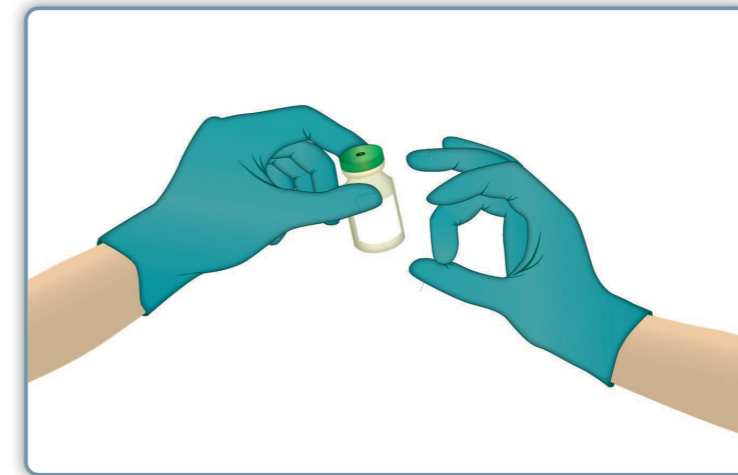
4. Close the internal opening(s) with an absorbable suture through the anal canal.



PRODUCT PREPARATION AND INJECTION

PREPARATION

- Before preparation re-confirm expiry date and time.
- Clearly record the name and the batch number of the product in the patient's medical file.
- Re-suspend the cells, Alofisel® vials, by gently tapping the bottom of the vials until a homogeneous dispersion is obtained, avoiding bubble formation. Each Alofisel vial should be used immediately after re-suspension to prevent the cells from re-sedimenting.

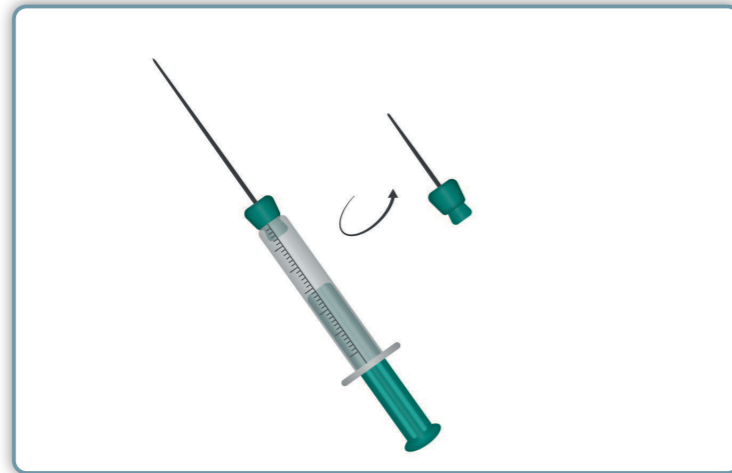


- To extract the contents of each vial, remove the green plastic cap to access the rubber seal, gently turn the vial upside down, and gently aspirate all contents using a syringe with a conventional needle no thinner than 22G.



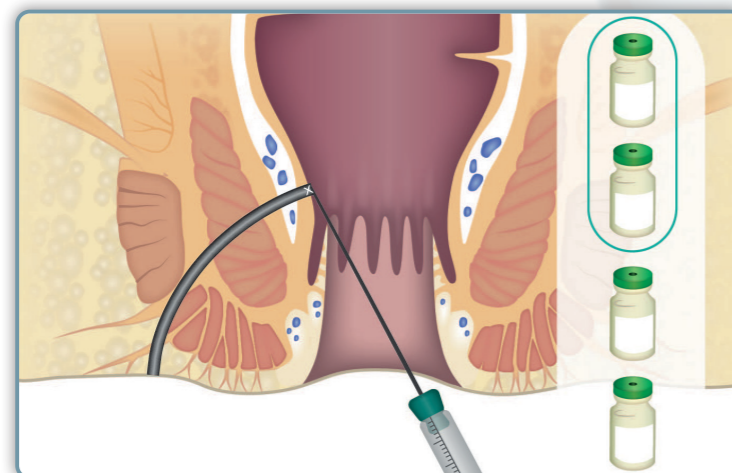
- In order to reach the internal opening(s), replace the aspiration needle by a longer needle, also no thinner than 22G. For example, a needle for spinal injection of about 90 mm length is appropriate for this purpose.

Thinner needles can cause cell disruption during injection, compromising the efficacy of treatment.



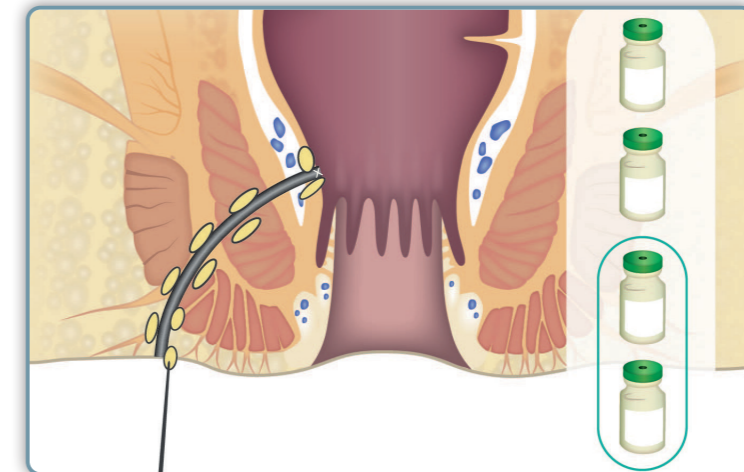
INJECTION

- Inject Alofisel® in the following way:
 1. Enter the needle through the anus and inject the contents of 2 vials into the tissue surrounding the internal opening. Make several small blebs to deposit the cell dispersion.
If more than one internal opening exists, distribute the contents of the 2 vials evenly into the tissue around both internal openings.



2. Enter the needle through the external opening and inject the content of the remaining 2 vials superficially into the tissue walls along the length of the fistula tract, again making several small blebs. Ensure that the product is not injected into the lumen of fistula tracts in order to avoid leakage of cells.

In the case that more than one tract is treated, the contents of the 2 vials should be distributed equally across all tracts.



- Softly massage the area of the external opening(s) for 20 to 30 seconds and close the external opening with a bandage.
- Discharge the patient according to the ambulatory surgery routine.

For further information please refer to the full Alofisel® Prescribing Information as approved by the Israeli MoH

חברת זו ותוכנה אושרו על ידי משרד הבריאות אוגוסט 2024



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